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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,766	09/22/2006	Frank Burkamp	T1655P	9140
	210 7590 99/24/2008 EXAMINER MERCK AND CO., INC		IINER	
P O BOX 2000 RAHWAY, NJ 07065-0907			BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			09/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.	Applicant(s)	_
10/593,766	BURKAMP ET AL.	
Examiner	Art Unit	_
/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
   Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
- earned patent term adjustment. See 37 CFR 1.704(b).

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	Responsive to communication(s) filed on <u>22 September 2006</u> .
	This action is FINAL. 2b) This action is non-final.
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.
spositi	on of Claims
4)🛛	Claim(s) 1-13 is/are pending in the application.
	4a) Of the above claim(s) is/are withdrawn from consideration.
5)	Claim(s) is/are allowed.
6)	Claim(s) is/are rejected.
7)	Claim(s) is/are objected to.
8)🛛	Claim(s) 1-13 are subject to restriction and/or election requirement.
plicati	on Papers
9)[	The specification is objected to by the Examiner.
10)	The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d)
11)	The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.
iority u	nder 35 U.S.C. § 119
12) 🔲 .	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)[	☐ All b)☐ Some * c)☐ None of:
	<ol> <li>Certified copies of the priority documents have been received.</li> </ol>
	<ol> <li>Certified copies of the priority documents have been received in Application No</li> </ol>
	3. Copies of the certified copies of the priority documents have been received in this National Stage
	application from the International Bureau (PCT Rule 17.2(a)).
* 8	see the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

1) Notice of References Cited (PTO-892)	
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 Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date \_\_\_\_\_

4)	Interview Summary (PTO-413)
	Paper No(s)/Mail Date
5)	Notice of Informal Patent Application
6)	Other:

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## DETAILED ACTION

Claims 1-13 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3 and 8-13, drawn to compound of formula I wherein X and  $T^4$  is nitrogen,  $T^1$  is C, Y and Z is  $C(CH_2)_nR^2$ , composition and method of use.

Group 2, claims 1-13, drawn to compound of formula I, wherein X, Y, Z, T<sup>1</sup> and T<sup>2</sup> are other than that provided for in Group I, composition and method of use. If this group is elected applicants should also elect specific X, Y, Z, T<sup>1</sup> and T<sup>2</sup>.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where there is lack of unity the requirement for restriction is proper- See MPEP 803.02. The requirement for unity of invention is two-fold: (1) common utility and (2) sharing a substantial structural feature disclosed as being essential to the utility. Both these conditions are to be met with. Instant claims do not meet both these conditions.

Invention I and II are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core, namely, isomeric pyrrolo-pyridiazine versus isomeric pyrrolo-tetrazine, versus isomeric pyrrolo-triazine,

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versus isomeric pyrrolo-pyrimidine versus pyrrolo-pyrazine, versus isomeric isomeric pyrrolo-pyridine cores. Consequently, the groups require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. For example prior art cited in the International Search Report and the Information Disclosure Statement may not be applicable to all the above groups. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Except for the NH group, and O-CO group, every ring and substituents in the core of compound of formula I is varied and it cannot be said that a ring bearing nitrogen and O-CO group essentially contribute to the utility recited in the claims. Thus, the common structural feature essential for the said utility is not met with.

In addition, common utility requirement is also not met with as evident from the claims that these compounds can be used for various inflammatory diseases including arteriosclerosis, arthritis, inflammatory bowel disease and rheumatoid arthritis and various pains. In addition, prior art cited in the Information Disclosure Statement and International search report clearly state other uses for the instant compounds. Thus, both the criteria set forth for unity of invention is not met with.

In view of distinct nature of each invention, the restriction requirement is set forth in writing.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

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and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification:
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries):
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement Application/Control Number: 10/593,766

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will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571)

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272-0662. The examiner can normally be reached on Monday through Thursday from

8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is

James O. Wilson, whose telephone number is (571) 272-0661. The fax phone number

for the organization where this application or proceeding is assigned (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status

information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624